K102651

510(K) SUMMARY

JAN 12 2011

Submitter's Name: iScreen Vision, Inc
110 Timbercreek Drive Suite #2
Cordova, TN 38018
Phone: (901) 201-6132
Fax: (901) 327-7705
Contact Person: Buck Brown, CEO

Name of Device: iScreen Vision Screener 3000

Common or Usual Name: Ophthalmic Camera

Classification Name and Product Code: Class II, Ophthalmic Camera – 21 C.F.R. § 886.1120

Predicate Devices: iScreen Vision Screener, K010315

Purpose of the Special 510(k) Notice: The iScreen Vision Screener 3000 is a modification of its predicate device, the iScreen Vision Screener, which was cleared under K010315.

Intended Use / Indications for Use: The iScreen Vision Screener 3000 is a vision screening tool intended to capture and record red reflex images which contain information on ocular status to aid in eye examination.

The iScreen Vision Screener 3000 is intended for use solely for a pediatric population by trained professionals.

Technological Characteristics: The iScreen Vision Screener 3000 uses the same operational principle as the predicate iScreen Vision Screener. The device consists of an illumination source and camera to record and measure the retinal reflex and ocular status for later analysis by an appropriate expert. Certain features of the device have been modified from the predicate design to enhance ease of use and in response to user feedback, *e.g.*, the patient positioning system has been modified. Other modifications include the addition of a second flash, a smaller form factor, and integration of the previously separate PC screen and keyboard into the device casing. These modifications do not affect the safety or effectiveness of the device as compared to its predicate.

Performance Data: The risk analysis method used to assess the impact of the modifications was a Failure Mode and Effects Analysis ("FMEA"). According to the results of the FMEA, the residual risks of the device are deemed acceptable in relation to

device benefits. Design verification and validation activities were performed as a result of this risk analysis and per device design controls.

Substantial Equivalence: The product has the same intended use and principle of operation as the iScreen Vision Screener, K010315. Modifications to the device do not raise new or different questions of safety or effectiveness for the device's intended use. The results of risk analysis and design verification and validation activities provide evidence that the device is as safe and effective as its predicate. This evidence therefore demonstrates that the iScreen Vision Screener 3000 is substantially equivalent to its predicate device, the iScreen Vision Screener.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

iScreen Vision, Inc.
c/o Mr. Buck Brown
CEO
110 Timber Creek Dr., Suite 2
Cordova, TN 38018

JAN 12 2011

Re: K102651
Trade Name: iScreen Vision Screener 3000
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulation Class: Class II
Product Code: HKI
Dated: December 10, 2010
Received: December 13, 2010

Dear Mr. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kevia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

JAN 12 2011

Indications for Use Statement

510(k) Number (if known): **K102651**

Device Name: iScreen Vision Screener 3000

Indications for Use:

The iScreen Vision Screener 3000 is a vision screening tool intended to capture and record red reflex images which contain information on ocular status to aid in eye examination.

The iScreen Vision Screener 3000 is intended for use solely for a pediatric population by trained professionals.

Prescription Use X (Per 21 C.F.R. 801.109) AND/OR Over-The-Counter Use____ (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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